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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,038	11/17/2000	Carlos Vonderwalde Freidberg	24079-1071	7272

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09/29/2004

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/716,038

Applicant(s)

FREIDBERG, CARLOS
VONDERWALDE

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 29, 30, 32, 35-38 and 41-49 is/are pending in the application.
- 4a) Of the above claim(s) 10-20, 32 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 29, 30, 35-38, 41-45 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Election/Restrictions

Claims 10-20, 32, and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4 dated June 3, 2002.

In view of the papers filed June 3, 2004, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Zvi Boms as an inventor.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 29, 30, 35-38, 41-45, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 1 and 29 and their dependent claims, the term "impervious" or "impervious so as to prevent tissue ingrowth" does not have original support and its scope is not clearly understood. For this reason, the Examiner posits that the term "impervious" constitutes new matter with respect to the originally filed specification and claims. In particular, the original specification does not use the terminology "impervious to tissue ingrowth". Rather, the specification only discloses a "relatively impervious" heterologous tissue that "prevents tissue buildup and migration of smooth muscle cells through the stent framework (emphasis added); see page 9, lines 4-6 of the original specification. In contrast, the claims state that the tissue is not relatively impervious, but rather "impervious." In addition, this relative impervious layer is not qualified as preventing tissue ingrowth in the original specification, but rather as a way of preventing "tissue buildup and migration of smooth muscle cells." Since the tissue layer of is not necessarily impervious to tissue ingrowth, it is not originally supported.

The Examiner suggests replacing the present claim language of "impervious so as to prevent tissue ingrowth" to what was originally disclosed in the specification. Alternatively, the Applicants could make a showing that the thinned tissue originally disclosed inherently prevents tissue ingrowth.

Rejections Based Upon Prior Art

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 9, 37, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) alone where the effective filing date of these claims is March 4, 2004 because of the new matter added to the claims. Winston discloses a thinned tissue on a stent where the tissue is thin enough to improve the viability of the graft and improve endothelial cell migration, but Winston fails to disclose the thickness of the tissue as claimed; see column 1, line 67 to column 2, line 4, column 2, lines 48-61, and column 3, lines 17-45, Figures 1-3, column 3, lines 16-59, and column 5, lines 4-20. However, the mere setting forth of a thickness is not considered sufficient to support patentability and would have been obvious to an ordinary artisan in the art. In particular, MPEP 2144.04 is incorporated herein by reference and states:

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

With regard to claim 9, Applicant is directed to Figure 3.

Claims 1-4, 6-9, 36, 37, 43-45, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love (WO 97/24081) in view of Winston et al (US 6,117,166). Love (WO) discloses a tubular support frame made of expandable material (spring steel

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or Nitinol, see page 10, lines 21-27) which is wrapped with pericardial tissue or similar tissues; see page 4, lines 12-29, page 5, lines 7-33, and page 9, lines 26-29. The tissue is impervious because it is impervious to blood; see page 4, lines 25-29. However, Love fails to disclose that the tissue is thinned as claimed.

Winston et al, however, teaches that it was known to thin tissue for similar devices such that the claimed thickness is obvious as a way to improve the viability of the implant; see the abstract and the previously cited portions. Hence, it is the Examiner's position that it would have been obvious to use thinned tissue in the Love device for the same reasons that Winston et al uses the same.

Furthermore, the mere setting forth of a thickness is not considered sufficient to support patentability and would have been obvious to an ordinary artisan in the art; there is no criticality set forth or shown for the less than 0.45 mm thickness range claimed. In particular, MPEP 2144.04 is incorporated herein by reference and states:

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

With regard to claim 36 specifically, Love teaches that it was known to have the inner and outer layers longer than the stent but not specifically by less than 5 % as claimed. However, since there is not criticality for this feature, it is the Examiner's position that it would have been prima facie obvious to match the length of the stent

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and tissue cover closely in order to reduce the cost of making the device and in order to prevent loose tissue ends from causing thrombosis of the vessel.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) in view of Narciso (WO 94/15583). Winston et al fails to include a therapeutic material in the graft thereof. Narciso teaches that it was known to use therapeutic materials in similar implants. Hence, it is the Examiner's position that it would have been obvious to do the same in Winston's device for the same reasons that Narciso does the same.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Love (WO 97/24081) and Winston (US 6,117,166) as set forth in the rejections of claims 1-4, 6-9, 36, 37, 43-45, and 47-49 and in further view of Dereume (US 5,653,747). Love renders the claim language obvious as set forth in the rejection of claims 1-4, 6-9, 36, 37, 43-45, and 47-49 above, but Love fails to teach the concept of having the jacket shorter than the stent or support as claimed. Dereume, however, teaches that it was known to make the graft slightly shorter than the stent or support; see the figures. Therefore, it is the Examiner's position that it would have been obvious to make the support of Love longer than the tissue graft is supports for the same reasons that Dereume does the same in the invention thereof.

Response to Arguments

Applicant's arguments filed August 8, 2004 have been fully considered but they are not persuasive.

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In response to the traversal of the Section 112, first paragraph rejection that there is support on page 9, lines 4-6 of the original specification, the Examiner asserts that there is no support for the previous language or the present language of the claims. Specifically, the term "impervious" or "impervious so as to prevent tissue ingrowth" does not have original support and its scope is not clearly understood. In particular, the original specification does not use the terminology "impervious to tissue ingrowth". Rather, the specification only discloses a "relatively impervious" heterologous tissue that "prevents tissue buildup and migration of smooth muscle cells through the stent framework" (emphasis added); see page 9, lines 4-6 of the original specification. In contrast, the claims state that the tissue is not relatively impervious, but rather "impervious." In addition, this relative impervious layer is not qualified as preventing "tissue ingrowth" in the original specification, but rather as a way of preventing "tissue buildup and migration of smooth muscle cells." Since the tissue layer of is not shown as being necessarily impervious to tissue ingrowth, it is not originally supported.

The Examiner suggests replacing the present claim language of "impervious so as to prevent tissue ingrowth" to what was originally disclosed in the specification. Alternatively, the Applicants could make a showing that the thinned tissue originally disclosed inherently prevents tissue ingrowth.

In traversing the Winston rejections, Applicant argues that the claims of the first rejection should be included with their independent claims. In response, the issue was made moot in view of the inclusion of claim 1 in the claim set before the previous Office action. The Examiner maintains that the rejection is still tenable.

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In response to the traversal that there is no unwrapping taught by Love or Winston in the second prior art rejection. In response, the Examiner has withdrawn some claims from the rejection such that the issue is moot and not commensurate with the present claim scope. Furthermore, the argument that the tissue of Love is not configured to be expanded is not relevant to the present claims that do not have such a limitation.

In response to the argument that Love does not teach that the tissue is impervious to ingrowth, the Examiner maintains that Love inherently does because it teaches impermeability to blood. If the tissue is impervious to blood, which contains water, it flows from this that it is also impervious to tissue cells and tissue ingrowth because the water molecule (at least 70% of water) is much smaller than a cell. Furthermore, since Love uses the same tissue in his invention as the Applicants do, it is inherently impervious to ingrowth as the claimed tissue is.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (703) 308-2111. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilit
Primary Examiner
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